American
Chemistry
Council Council

COURTNEY M. PRICE VICE PRESIDENT CHEMSTAR

July 10, 2003

Ms. Linda Fisher Acting Administrator U.S. Environmental Protection Agency P.O. Box 1473 Merrifield, VA 22116

The American Chemistry Council Brominated Biocides Panel HPV Submission for 5,5-Dimethylhydantoin, CAS No. 77-71-4 (Consortium Number

Dear Ms. Fisher:

Re:

The American Chemistry Council (ACC) Brominated Biocides Panel DMH Task Force (Task Force) is pleased to submit the enclosed 5,5-dimethylhydantoin (DMH) Test Plan under the US EPA Voluntary HPV Chemical Challenge Program. The Test Plan includes: 1) summary of available and adequate studies to fulfill HPV SIDS endpoints for DMH; 2) modeling information for DMH; and 3) robust data summaries for DMH on HPV SIDS endpoints.

The Task Force serves as an industry consortium to coordinate activities for DMH under the HPV Program. The Task Force member companies who have voluntarily committed to sponsor DMH under the HPV Chemical Challenge Program include: Ameribrom, Inc.; BioLab, Inc.; and Lonza Inc.

The original commitment to sponsor DMH under the HPV Program was communicated to EPA on November 30, 1999. In subsequent letters of October 17, 2001 and December 13, 2002, the Task Force notified the Agency of an extension in submitting the Test Plan to maintain the proprietary information from becoming publicly available before the Notification deadline under the EU Biocidal Products Directive (BPD). The BPD Notification period closed earlier this year, and therefore the Task Force is now submitting its DMH Test Plan to EPA. DMH data have been used to support halohydantoin product registration in many countries. Currently, EPA is relying on DMH data for halohydantoin Reregistration Eligibility Decision.

The Panel believes that the data presented in this submission are adequate to satisfy the US EPA Voluntary HPV Chemical Challenge Program for DMH, and that no additional testing is required.



Responsible Care*

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This letter and the attached Test Plan are also being sent electronically to the following e-mail addresses:

Oppt.ncic@epa.gov Chem.rtk@epa.gov

Please feel free to call Has Shah, Manager, DMH Task Force, at 703/741-5637, if you have any questions or need additional information.

Sincerely yours,

Courtney M. Price Vice President, CHEMSTAR

Enclosure

cc:

Brominated Biocides Panel DMH Task Force

Jim Keith